Supreme Court, U.S.
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No. 04-607

IN THE
Supreme Court of the United States

LABORATORY CORPORATION OF AMERICA HOLDINGS (doing business as LabCorp),

Petitioner,

v.

METABOLITE LABORATORIES, INC. and COMPETITIVE TECHNOLOGIES, INC.,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

SUPPLEMENTAL BRIEF FOR PETITIONER IN RESPONSE TO BRIEF FOR THE UNITED STATES

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TABLE OF CONTENTS

		Page
TABLE OF AUTHORITIES		ii
I.	THE UNITED STATES' OWN REASONING DEMONSTRATES THE PATENT'S INVALIDITY	1
II.	THE ISSUE IS PROPERLY BEFORE THE COURT	5
III.	CERTIORARI OR GVR IS WARRANTED	9
CONCLUSION		10

TABLE OF AUTHORITIES

	Page
CASES:	
Barkeij v. *Lockheed Aircraft Corp.*, 210 F.2d 1 (9th Cir.), *cert. denied*, 348 U.S. 847 (1954)	6
Diamond v. *Chakrabarty*, 447 U.S. 303 (1980)	2
Diamond v. *Diehr*, 450 U.S. 175 (1981)	1, 4, 5, 6-7, 9
Funk Bros. Seed Co. v. *Kalo Inoculant Co.*, 333 U.S. 127 (1948)	2, 4
Gottschalk v. *Benson*, 409 U.S. 63 (1972)	3, 4
Hill v. *Wooster*, 132 U.S. 693 (1890)	6
Howes v. *Great Lakes Press Corp.*, 679 F.2d 1023 (2d Cir. 1982), *cert. denied*, 459 U.S. 1083 (1983)	6
Metro-Goldwyn-Mayer Studios Inc. v. *Grokster, Ltd.*, 125 S. Ct. 2764 (2005)	10
Parker v. *Flook*, 437 U.S. 584 (1978)	4, 9
Slawson v. *Grand St. R.R.*, 107 U.S. 649 (1883)	6
Smithkline Beecham Corp. v. *Apotex Corp.*, 403 F.3d 1331 (Fed. Cir. 2005)	6
T.H. Symington Co. v. *National Malleable Castings Co.*, 250 U.S. 383 (1919)	7
RULES:	
S. Ct. R. 14.1(a)	5
S. Ct. R. 15.2(a)	5-6
S. Ct. R. 15.8	1

SUPPLEMENTAL BRIEF FOR PETITIONER

Pursuant to S. Ct. R. 15.8, petitioner LabCorp responds to the brief filed by the Solicitor General at the Court's invitation. The Court asked for the views of the United States on a straightforward yes-or-no question. The Court expressly asked the Solicitor General to assume that the patent claimed only a two-step method—(1) "measure the level of the relevant amino acids using any device, whether the device is, or is not, patented" and (2) "notice whether the amino acid is elevated and, if so, conclude that a vitamin B deficiency exists." The Court then asked whether that patent claim, as so construed, is invalid "because one cannot patent 'laws of nature, natural phenomena, and abstract ideas.' " 125 S. Ct. 1413 (citing *Diamond* v. *Diehr*, 450 U.S. 175, 185 (1981)).

The Solicitor General's brief, however, does not answer the question. If it had, the answer would have to have been "yes." For the United States' *own* reasoning shows that the construction of the patent posited by the Court—which accurately conveys the Federal Circuit's basic holding—would render the patent invalid. According to the Federal Circuit, Claim 13 is infringed whenever a doctor looks at a homocysteine test result—*regardless* of how the test result was obtained—and *thinks in his or her mind* that it may signify a vitamin deficiency. As the United States' own brief (and common sense) demonstrate, such an attempt to monopolize a basic scientific correlation is impermissible. No further factual development is needed to reach that result. Moreover, that basic question is squarely presented by the decision below, was posed in the petition for certiorari and below, and is also a fundamental legal question that the Court can and should answer for itself. The petition should be granted.

I. THE UNITED STATES' OWN REASONING DEMONSTRATES THE PATENT'S INVALIDITY

The United States admits that "Claim 13 appears to *involve* * * * a [non-patentable] natural phenomenon, because it

asserts and relies on the existence of a naturally occurring correlation between elevated levels of total homocysteine and deficiencies in cobalamin or folate." U.S. Br. 6 (emphasis in original). But it then incorrectly suggests that further factual development "may" (*id.* at 5) be warranted to address the specific question posed by this Court. The Court did not ask the Solicitor General to reflect on other possible constructions of Claim 13 *not* adopted by the Federal Circuit; it paraphrased the Federal Circuit's construction and asked whether *that* construction would render the claim invalid for seeking to patent a law of nature. The Federal Circuit construed Claim 13 as claiming a scientific correlation rather than any inventive application of it. No further factual development is needed to determine that this construction cannot stand.

The United States correctly observes that the "natural relationship between elevated total homocysteine and deficiencies in the B vitamins" is unpatentable "just as the relationship between energy, mass, and the speed of light discovered by Einstein ($E=mc^2$), and the relationship between force of attraction, mass, and distance discovered by Newton (the law of gravity), are unpatentable natural phenomena." U.S. Br. 6 (citing *Diamond* v. *Chakrabarty*, 447 U.S. 303, 309 (1980)). *See Funk Bros. Seed Co.* v. *Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948) (natural phenomena, "like the heat of the sun, electricity, or the qualities of metals" are "manifestations of laws of nature, free to all men and reserved exclusively to none") (cited at Pet. 18, 26). But the Solicitor General then opines that further facts may be needed to determine whether Claim 13 seeks such an impermissible monopoly. That is wrong. Under the United States' *own* reasoning, the liability imposed by the Court of Appeals is impermissible.

The Federal Circuit construed the patent as bestowing the right to prevent any doctor from merely *thinking* about a basic scientific correlation when treating patients. The court held that Claim 13 is infringed whenever a doctor looks at a homocysteine test result—no matter the reason or method for

performing the test—and *thinks* that the result might signify a vitamin deficiency (*i.e.*, "correlates"). Allowing such a claim would "wholly pre-empt" a natural principle and "in practical effect would be a patent on the [correlation] itself." *Gottschalk* v. *Benson*, 409 U.S. 63, 72 (1972). Using the United States' own example taken from this Court's precedents, if respondents were correct here, Einstein could have prevented any physicist from thinking about his famous equation simply by drafting the patent claim "test for E and correlate with mc^2" or "test for m and correlate with E/c^2."

The Solicitor General opines that Claim 13 might not seek a monopoly over a law of nature because various methods of *assaying* for homocysteine "entail significant physical or chemical alteration of a blood or fluid sample." U.S. Br. 9. But that argument ignores the fundamental fact that *Claim 13 applies regardless of how the assay is conducted.* The inventive, transformative assay method the United States describes, *id.* at 9-10, is set forth in *different* patent claims not at issue in this case—and LabCorp continues to pay royalties whenever it uses that patented method. Claim 13 asserts as private intellectual property the act of "correlating" (wholly in one's mind) *any* test result against a scientific fact.

The Solicitor General thus misses the point when he suggests that "[t]he record is * * * not well developed" as to whether the process claimed in Claim 13 includes every "practical application" of the natural relationship between homocysteine and vitamin deficiencies. *Id.* at 10 (internal quotations omitted). Claim 13 purports to patent the mental act of thinking about a test result. The record need not be developed to flesh out all of the possible ways to test or think, for they are all embraced within that claim. There are similarly many different ways to measure energy or mass, some of which might be patentable on their own, but that would not have allowed Einstein to patent a method claiming no more than "test for energy and correlate with mass times the speed of light squared." No "factual development" would

be required to determine that such a patent claim was invalid, and no further factual development is required here.[1]

The trivial requirement that an assay be conducted before "correlating" cannot transform Claim 13 into a novel invention, because the correlation itself embodies the obvious notion that a homocysteine level somehow be observed. The assaying step—which can use *any* method, patented or not—is precisely the kind of "token" activity that, under this Court's cases, cannot disguise respondents' attempt to claim a monopoly over the correlation itself. "The process itself, not merely the mathematical algorithm, must be new and useful." *Parker* v. *Flook*, 437 U.S. 584, 591 (1978). One cannot patent an unpatentable principle merely by grafting onto it a non-inventive use. *Id.* at 590. *See Funk Bros.*, 333 U.S. at 130 (a "hitherto unknown phenomenon of nature" is not patentable; only "the application of the law of nature to a new and useful end" is). Thus, "a mathematical formula does not become patentable subject matter merely by including in the claim for the formula token postsolution activity * * *." *Diehr*, 450 U.S. at 192 n.14. Unlike the patent in *Diehr*, which claimed a complex "industrial process" for molding rubber products rather than just a "mathematical formula," *id.* at 192-193, Claim 13, as construed by the Federal Circuit, involves *no* inventive process beyond the correlation itself.

"Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work." *Gottschalk*, 409 U.S. at 67. Applying that principle here would *not* call into question all "patents on medical di-

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[1] Regardless, the mere *possibility* that the Court might need to remand for proceedings applying the facts to legal principles established by its decision is no basis for allowing the erroneous decision here to stand. To borrow the Solicitor General's phrase, there is "at least some possibility" (U.S. Br. 18) that such a remand may be warranted in virtually any case that reaches this Court.

agnostic methods" or "computer-related processes." U.S. Br. 14. After all, the claims of this patent asserting a particular method of testing for homocysteine are unchallenged, and LabCorp continues to pay royalties for that method. Claim 13, by contrast, seeks a monopoly over the thought processes of doctors. Invalidating that claim will not affect truly inventive diagnostic methods. To the contrary, it will advance public health by preventing respondents and others from patenting the right to prevent doctors from merely thinking about medical facts necessary for sound medical treatment.

II. THE ISSUE IS PROPERLY BEFORE THE COURT

Rather than answer the question posed by the Court, the Solicitor General spends much of his brief opining on whether the Court should, as a prudential matter, decide it. To be clear, as the United States itself acknowledges, there is no *jurisdictional* impediment to reaching this issue, which the Court has "inherent discretion" to consider. U.S. Br. 16. In any event, the basic question was posed in the petition and below and there is no reason for the Court not to reach it.

This Court will consider any question "fairly included" in the questions presented. S. Ct. R. 14.1(a). Here, the questions presented asked, *inter alia*, whether a patent "directing a party simply to 'correlat[e]' test results can validly claim a monopoly over a basic scientific relationship used in medical treatment." Pet. i. The body of the petition, moreover, extensively addressed the question posed in the Court's invitation order, citing and relying on not only *Diehr*, but other precedents to the same effect. *See, e.g.*, Pet. 18, 19, 25-26, 27, 29; *see also* Pet. Reply 6.

Rule 15.2 "admonishe[s]" respondents' counsel "to point out in the brief in opposition and not later, any perceived misstatement made in the petition," and states that "[a]ny objection to consideration of a question presented based on what occurred in the proceedings below, if the question does not go to jurisdiction, may be deemed waived unless called to the Court's attention in the brief in opposition." S. Ct. R.

15.2(a). Yet respondents' brief in opposition nowhere objects to consideration of this issue based on what occurred below or otherwise. The issue is therefore squarely before the Court. Indeed, even when the question of patentability is *not* raised by the parties, it has been settled for more than a century that courts can and should address that important issue in adjudicating a claim for patent infringement.[2]

But the question posed by this Court was also posed below. In the Court of Appeals, LabCorp expressly argued that

> [i]f the Court were to uphold this vague claim, anyone could obtain a patent on any scientific correlation—that there is a link between fact A and fact B—merely by drafting a patent claiming no more than "test for fact A and correlate with fact B," without any explanation of the testing or correlation processes. Claim 13 does no more than that. If it is upheld, CTI would improperly gain a monopoly over a basic scientific fact rather than any novel invention of its own. The law is settled that no such claim should be allowed. *See, e.g.*, *Diamond* v.

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[2] *See, e.g.*, *Hill* v. *Wooster*, 132 U.S. 693, 698 (1890) ("neither the Circuit Court nor this court can overlook the question of patentability"); *Slawson* v. *Grand St. R.R.*, 107 U.S. 649, 652 (1883) ("If letters patent are void because the device or contrivance described therein is not patentable, it is the duty of the court to dismiss the cause on that ground whether the defense be made or not. * * * Every suitor in a cause founded on letters patent should, therefore, understand that the question whether his invention is patentable or not, is always open to the consideration of the court, whether the point is raised by the answer or not."); *Smithkline Beecham Corp.* v. *Apotex Corp.*, 403 F.3d 1331, 1352-55 (Fed. Cir. 2005) (Gajarsa, J., concurring); *Howes* v. *Great Lakes Press Corp.*, 679 F.2d 1023, 1028 (2d Cir. 1982) (patentability "deals with the subject matter of patents and, as such, it is 'always open to the consideration of the court'") (citation omitted); *Barkeij* v. *Lockheed Aircraft Corp.*, 210 F.2d 1, 2 (9th Cir. 1954) ("it is the duty of the court to dismiss a patent infringement suit whenever it affirmatively appears that the patent is invalid").

> *Diehr*, 450 U.S. 175, 185 (1981) ("[e]xcluded from * * * patent protection are laws of nature, natural phenomena, and abstract ideas"); Chisum on Patents § 1.03[6].

LabCorp Ct. App. Br. at 41.

The issue also arose in the trial court; indeed, it was raised *by the court itself*. In construing Claim 13, the court held that " '[c]orrelating' is a verb, and must * * * comprise a discrete, sequential process step." A221. And it further stated

> [A]n invention is not just an idea, it is not just a mental discovery. It must combine the idea with the means of putting it into practice and producing the desired result. And so until the discovery is put into a practical form, there is no invention. There is no valid patent. * * * The Supreme Court, way back when, in [*T.H. Symington Co.* v. *National Malleable Castings Co.*, 250 U.S. 383 (1919)], said "A conception of the mind, not represented in some physical form, is not an invention." So if one takes the statement, which may very well be a wonderful new conception, that if there is an elevated level of total homocysteine and * * * that elevated level can be correlated in said body fluid with deficiency of cobalamin or folate, that is certainly a new idea, something original. But what is the * * * practical form of that? What are the actual steps? What are the discrete, sequential steps for putting into practice this new statement?

A3046-47 (*Markman* hearing transcript). As the court reiterated at trial "[b]asically, what my ruling was is that *you can't patent an idea. You have to patent an act or the test* * * *." A4662-63 (emphasis added).[3]

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[3] *See also* A3057 (trial court direction to "[t]ell me what practical steps are done to do [the correlating]? Because we know from the case law that there must be a practical form. Can't be just a mental conception. So what do you do? No. 1, No. 2, No. 3, No. 4. What do you do to correlate?"); Trial Tr., Vol. IX, at 1689 (trial court statement that "it's difficult to think you can patent an idea,

Thus, the trial court had ruled that Claim 13 would invalidly claim a monopoly over a law of nature unless "correlating" comprised an active step beyond simply thinking about the correlation, and had incorporated that requirement into its claim construction. On that premise, LabCorp consistently argued below that the patent should be construed to require evidence of this step needed to save it from invalidity, or else it would be hopelessly ill-defined. For example, in seeking a new trial or JMOL, LabCorp argued that there was no evidence that doctors engaged in a "discrete, sequential process step" as the claim construction had required to avoid the invalidity problem and, relatedly, that the patent provided no definite guidance as to how this discrete process step was to be accomplished. *See, e.g.*, LabCorp Renewed Motion for JMOL at 5 ("As interpreted by the Court, the second step of claim 13 must be 'a discrete step in a sequential process.' The Court has held that the second step must be an active step—a mental step is insufficient.") (R. 249).

The Solicitor General is therefore wrong to assert that the lower courts did not construe the claim with the inventiveness requirement in mind. U.S. Br. 17-18. The District Court initially did just that, and the Federal Circuit simply ignored the dangerous invalidity implications—specifically raised by LabCorp—of not requiring a further active step beyond thinking about the correlation. The Solicitor General says that there is "some possibility that the correlation step might be construed to entail a more involved medical diagnosis, beyond the simple mental step envisioned by the court of appeals' decision and this Court's question." *Id.* at 18. But LabCorp raised that *precise* argument in the Federal Circuit, *see* LabCorp Ct. App. Br. 23-25, 27-29, specifically informing the court that upholding such an ill-defined claim

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rather than a test. And that's what I'm afraid some of these patents do, is try to patent an idea."); *id.* at 1707 (trial court statement that "[l]ets talk about whether you really can patent an idea, though, rather than a method * * *. This is part of the argument.").

would render it invalid under *Diehr*, *id.* at 41. However, the Federal Circuit, at respondents' urging, expressly rejected the argument, wrongly construing Claim 13 to require no further step beyond rote mental application of the correlation.

Accordingly, the question whether that construction would render the patent invalid is properly and squarely before this Court, either by itself or in connection with LabCorp's other challenges to the Federal Circuit's decision.

III. CERTIORARI OR GVR IS WARRANTED

Defending the Patent and Trademark Office—which issued this defective patent in the first place—the Solicitor General urges the Court not to "overturn[ ] PTO's approach." U.S. Br. 14. Indeed, one wonders whether the Solicitor General's focus on matters outside the Court's invitation order is simply an effort to avoid review of the PTO's own practices. In any event, the Solicitor General's own reasoning shows that the case is an important one that warrants certiorari.

As the petition explains, respondents' attempt to monopolize *all* homocysteine testing is itself an issue of extraordinary national importance. The Solicitor General now admits that the case involves "a fundamentally important issue" that also potentially calls into question other patents on diagnostic methods. *Id.* at 14-15. Although truly inventive methods will be unaffected, *supra* at 5, the "PTO's approach," if allowed to stand, would in fact open the floodgates to monopolization of virtually *any* scientific correlation merely by drafting a vague "test plus correlate" claim. The Solicitor General also opines that the case implicates unresolved "tension" between this Court's decisions in *Diehr* and *Flook*, *id.* at 12, which the Federal Circuit has resolved for itself by holding that *Diehr* silently "superseded" *Flook*. *Id.* at 13. The result is the expansive view of patentability that led to the decision below. Whether or not the PTO—whose power extends as far as the patent laws—thinks that is a good idea, the admitted confusion in the law underscores the need for the Court to clarify this "fundamentally important issue."

Finally, as LabCorp anticipated in its first supplemental brief, certiorari or GVR is warranted in light of the Court's new decision in *Metro-Goldwyn-Mayer Studios Inc.* v. *Grokster, Ltd.*, 125 S. Ct. 2764 (2005). *Grokster* is the Court's first extensive examination of the law of induced infringement, which the Court held was identical in both patent and copyright law. *Id.* at 2780. The Court did not resolve the issue dividing the Federal Circuit and raised in this case—the standard for intent to induce—and certiorari is thus still warranted on that question. *See* Pet. 12-19. But just as the Court remanded *Grokster* for application of its new standard to the facts of that case, 125 S. Ct. at 2782-83, the Court should at a minimum remand this case for further consideration under that new standard. Indeed, remand is even more appropriate here. For unlike *Grokster*, which involved substantial evidence that the defendants specifically intended to encourage piracy, *id.* at 2772-74, 2780-82, the Federal Circuit found the requisite intent here based *solely* on LabCorp's dissemination of truthful medical information. The patent laws cannot allow respondents to prevent doctors from thinking about a scientific fact in treating patients, or to prevent others from informing doctors about that basic fact.

CONCLUSION

For the foregoing reasons, and those in the petition, the petition should be granted and the judgment below reversed.

Respectfully submitted,

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